K032646

NOV 1 2 2003

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3544

Contact Person: Kay A. Taylor

Date Prepared: August 26, 2003

Device Name

Proprietary name: Elecsys® proBNP Immunoassay

Common name: proBNP test

Classification name: Test, Natriuretic Peptide

Device Description

A device for the measurement of human proBNP in serum or plasma.

Intended use

For the quantitative determination of N-terminal pro-Brain natriuretic peptide.

Indications for Use

Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure.

510(k) Summary, Continued

Substantial equivalence

The device and test method contained within this premarket notification and described in the labeling is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Elecsys proBNP (K022516). Both products are intended for use in the quantitative determination of brain natriuretic peptides.

The Triage BNP test (K021317) is used as predicate method for the conceptual description of how a biochemical marker can be used to provide prognostic information to a physician. Although this predicate method describes a different analyte, the description of how the test results should be interpreted with respect to the prognosis of the patient are substantially equivalent.

Substantial equivalence – comparison

The following table compares the Elecsys proBNP Immunoassay with the predicate devices.

Table 3 - Comparison to Predicate Device

Feature	Elecsys proBNP (K022516)	Elecsys proBNP (add'l indication)	Triage BNP (K021317)
Intended Use	Immunoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic Peptide in human serum and plasma.	Imunnoassay for the in vitro quantitative determination of N-terminal pro-Brain natriuretic peptide in human serum and plasma.	The Triage BNP test is intended for use with the Triage Meter for the rapid in vitro quantitative measurement of B-Type Natriuretic Peptide (BNP) in human whole blood or plasma specimens using EDTA as the anticoagulant.
Indication for Use	The Elecsys proBNP is intended for use as an aid in the diagnosis of individuals suspected of having congestive heart failure.	Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure.	The test is used as an aid in the diagnosis and assessment of severity of congestive heart failure. The test also is used for the risk stratification of patients with acute coronary syndromes.
Assay Protocol	Electrochemiluminescent Immunoassay	Same Elecsys proBNP (K022516)	Fluorescence immunoassay
Traceability / Standardization	Reference standard - purified synthetic NTG-proBNP (1-76) in human serum matrix	Same Elecsys proBNP (K022516)	Not available

Feature	Elecsys proBNP (K022516)	Elecsys proBNP (add'l indication)	Triage BNP (K021317)
Calibration Interval	E170/E2010 • After 1 month when using the same reagent lot • After 7 days when using the same reagent kit E1010 • With every reagent kit • After 7 days (20-25°C) • After 3 days (25-32°C)	Same Elecsys proBNP (K022516)	Per lot
Sample Type	Human serum and plasma	Same Elecsys proBNP (K022516)	EDTA whole venous blood or plasma
Reagent Stability	Unopened • Up to stated expiration date stored at 2-8°C Opened • 12 weeks at 2-8° • 8 weeks on E170 • 8 weeks on E2010 • 4 weeks on E1010 (20-25° ambient temp - up to 20 hours opened in total)	Same Elecsys proBNP (K022516)	In sealed pouch • if stored refrigerated until the expiration date printed on the device • if stored at room temperature for 14 days (w/I expiration) • do not remove device from pouch until ready to use.
Calibrator	Elecsys proBNP CalSet	Same Elecsys proBNP (K022516)	Reagent Code Chip
Controls	Elecsys PreciControl proBNP	Elecsys PreciControl proBNP Elecsys PreciControl Cardiac	Triage BNP Controls
Result Interpretation	125 pg/ml for patients younger than 75 years and 450 pg/ml for patients 75 years and older.	Same Elecsys proBNP (K022516)	100 pg/ml

Feature	Elecsys proBNP (K022516)	Elecsys proBNP (add'l indication)	Triage BNP (K021317)
Instrument	Elecsys 1010, Elecsys 2010 and MODULAR analytics E170 family of analyzers	Same Elecsys proBNP (K022516)	Triage Meter
Measuring Range	5-35,000 pg/mL	Same Elecsys proBNP (K022516)	5 – 5000 pg/ml

Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys proBNP Immunoassay and the predicate device are compared in the table below.

Table 4 - Comparison to Predicate Device - Performance Characteristics

Feature	Elecsys proBNP (add'l indication)	Elecsys proBNP (K022516)	Triage BNP (K021317)
Precision	E170 - Within run 0.9%CV @ 474 pg/mL 1.1%CV @ 8005 pg/mL 0.9%CV @ 13682 pg/mL E170 - Total 5.8%CV @ 494 pg/mL 4.1%CV @ 7827 pg/mL 3.7%CV @ 13143 pg/mL E1010/2010 – Within run 2.7%CV @ 175 pg/mL 2.4%CV @ 355 pg/mL 1.9%CV @ 1068 pg/mL 1.8%CV @ 4962 pg/mL E1010/2010 – Total 3.2%CV @ 175 pg/mL 2.9%CV @ 355 pg/mL 2.6%CV @ 1068 pg/mL 2.3%CV @ 4962 pg/mL	Same Elecsys proBNP (K022516)	Within Day 8.8%CV @ 71.3 pg/mL 11.0%CV @ 629.9 pg/mL 11.6%CV @ 4087.9 pg/mL Total 9.9%CV @ 71.3 pg/mL 12.0%CV @ 629.9 pg/mL 12.2%CV @ 4087.9 pg/mL

Feature	Elecsys proBNP (add'l indication)	Elecsys proBNP (K022516)	Triage BNP (K021317)
Hook Effect	No effect up to 300,000 pg/ml	Same Elecsys proBNP (K022516)	Not available
Analytical Sensitvity	5 pg/mL	Same Elecsys proBNP (K022516)	< 5 pg/ml
Limitations	• No interference from bilirubin up to 35 mg/dL • No interference from hemoglobin up to 1.4 g/dL • No interference from triglycerides up to 4000 mg/dL • No interference with biotin up to 30 ng/mL • No interference from rheumatoid factor up to 1500 IU/mL • In patients receiving high biotin doses > 5 mg/dL, sample should not be taken until 8 hours after administration. • Rare occurrence of interference from high titers of anti-streptavidin and ruthenium • Use in conjunction with patient medical history, clinical exam and other findings	Same Elecsys proBNP (K022516)	• No interference from bilirubin up to 20 mg/dL • No interference from hemoglobin up to 10,000 mg/dL • No interference up to cholesterol up to 1,000 mg/dL • No interference up to triglycerides up to 1,000 mg/dL • No significant effect from hematocrit between 27% and 51%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor, MT (ASCP), RAC
Regulatory Program Principal
Centralized Diagnostic Submissions
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46256

NOV 12 2003

Re: k032646
Trade/Device Name: Elecsys® proBNP Immunoassay
Regulation Number: 21 CFR § 862.1117
Regulation Name: B-type natriuretic peptide test system (BNP)
Regulatory Class: II
Product Code: NBC
Dated: August 26, 2003
Received: August 27, 2003

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A

Device Name:

Elecsys® proBNP Immunoassay

Indications For Use:

For the in vitro quantitative determination of N-terminal proBrain natriuretic peptide in human serum and plasma.

Elecsys proBNP is used as an aid in the diagnosis of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010, Elecsys 2010 and MODULAR ANALYTICS E170 immunoassay analyzers

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032646